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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/091,561	08/21/1998	JEAN PLOUET	USB95ARCNR	5078

466 7590 06/18/2002

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
Serial Number: 09/091,561
Filing Date: 8/21/98
Appellant(s): Plouet et al.
Appellant's Representative: Philip A. DuBois

The examiner requests the opportunity to present arguments at the oral hearing.

Thank you for your attention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

10/20/03

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
October 20, 2003

Office Action Summary

Application No.	Applicant(s)
09/091,561	Plouet et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 25, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-35* is/are pending in the application.

4a) Of the above, claim(s) *18-24 and 31* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *25-30 and 32-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's Amendment, Remarks, and 1.132 declarations of Jean Plouet, Pierre Fons, and Pierre-Andre Cazenave, filed 3/25/02, are acknowledged. Upon further consideration, the rejection of Claim 30 under the first paragraph of 35 U.S.C. 112 for the recitation of new matter in the claim has been withdrawn.

2. Claims 25-30 and 32-35 are being acted upon.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-30 and 32-35 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation, for the reasons of record set forth in Paper No. 24, mailed 9/25/01.

Applicant's arguments, filed 3/25/02, have been fully considered but have not been found persuasive. Applicant argues that:

"The outstanding Official Action contends on page 3 that the method of the present invention would only give rise to a polyclonal antiserum. The Official Action contends that the production of monoclonal antibodies requires several additional screening and isolation steps.

"However, it is respectfully submitted that one of ordinary skill in the art would appreciate and know how to produce a monoclonal antibody from the polyclonal antiserum of the present invention.

"While it is true that the polyclonal antiserum of the present invention would give rise to a mixture of antibodies in which some would bind flk-1, some would bind flt, and some antibodies would bind both, it is respectfully submitted that the polyclonal antiserum would contain a sufficient proportion of antibodies binding flk but not flt. Once the polyclonal antiserum of the present invention is obtained, one of ordinary skill in

the art would be able to obtain the desired monoclonal antibody."

Thus, it appears that Applicant essentially agrees with the Examiner's position that A) the method set forth in the instant specification would result in a polyclonal antibody, and B) said antibody would not be the antibody of the instant claims. Applicant's argument appears to be that the production of the actual antibody of the instant claims would require additional steps which one of ordinary skill in the art would be able to perform. As such, it remains the Examiner's position that the specification does not disclose how to actually make the invention of the instant claims as is required. It remains the Examiner's position that if one of skill in the art performed the method disclosed in the specification said method would not result in the product of the instant claims. The Examiner again cites the declaration of Inventor Plouet, filed 9/11/00, which indicate that in one experiment, 3/4 of the antibodies produced were not specific for flk-1. A polyclonal antiserum (from which a polyclonal antibody would be isolated) would be expected to comprise a mixture of antibodies, some would bind flk-1, some would bind flt, and some would bind both. Said polyclonal antibody then could not meet the limitations of the claims.

Applicant has also submitted three new 1.132 declarations in support of the antibody of the instant claims. The declaration of Inventor Plouet asserts that 15-20% of the rabbits immunized by the methods of the instant claims would produce the anti-idiotypic antibody of the instant claims, and presumeably *only* the antibody of the instant claims. The inventor is asserting that approximately 1 in 5 rabbits produce what is essentially an monoclonal antibody after immunization with a multivalent antigen, and that mice would do the same. This must certainly be considered incredible, i.e., an extremely unexpected result, as the assertion flies in the face of basic tenants of antibody production, i.e., the polyclonal antibody response (see for example Harlow et al., Antibodies, 1988). As such, said assertion would require significant data in support. Further, the Inventor's vague assertion that a comparable percentage of mice would be expected to produce the same antibody "without undue experimentation, when following most of the steps described in the specification," is insufficient support of the claimed invention. It is noted that the support previously submitted, i.e., the 9/29/00 declaration of Inventor Plouet, taught only the production of a monoclonal antibody, whereas the instant claims are drawn to a polyclonal antibody.

Regarding the declaration of Pierre Fons, the declarant states "I produced several hybridomas," and "It took only routine experimentation to isolate and identify anti-id immunoglobulins from mice corresponding to the Ig2 J fraction of present application." Thus, it appears that first, the declarant produced monoclonal antibodies and second, additional steps (isolation and identification), not disclosed in the specification were required. It remains then the Examiner's position that if one of skill in the art performed the method disclosed in the specification said method would not result in the product of the instant claims.

Regarding the declaration of Pierre-Andre Cazenave, the declarant reiterates the assertions of Inventor Plouet. See the Examiner's response, above. However, the declarant also states that "it is only a matter of time and routine experimentation to produce monoclonal antibodies from potential B-lymphocytes and to identify those having the claimed binding specificity." This statement would seem to support the Examiner's position that, A) the antibody of the instant claims must be a monoclonal antibody, and B) the methods disclosed in the specification would not result in said antibody.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or

relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
June 6, 2002

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600